

MR-1 REPORT CHECK OFF LISTCompany : **Amneal Pharmaceuticals Corp.**

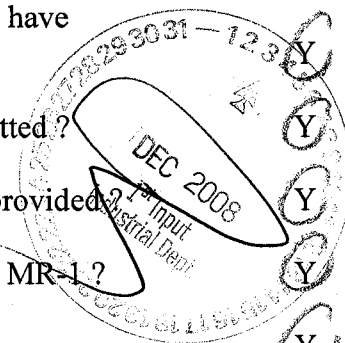
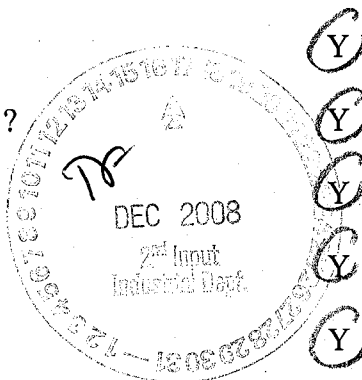
SCP #: 27200050-1

Address : 290 McClean Blvd., Paterson, NJ 07504

Contact : Jiten Parikh

973-357-0222

- | | | | | |
|-----|---|------------------------------------|------------------------------------|--------------------------------------|
| 1. | Category 40 CFR 439.47 (b) Subcategory | D | | |
| 2. | MONTH OF OCTOBER 1, 2008 THRU OCTOBER 31, 2008 | | | |
| 3. | Is Outlet # (8 digit) Correct ? | <input checked="" type="radio"/> Y | N | N/A |
| 4. | Is regulated flow stated in space provided ? | <input checked="" type="radio"/> Y | N | N/A |
| 5. | Total flow provided in proper space ? | <input checked="" type="radio"/> Y | N | N/A |
| 6. | Is method used to calculate water stated,? | <input checked="" type="radio"/> Y | N | N/A |
| 7. | Are number of working days stated ? | <input checked="" type="radio"/> Y | N | N/A |
| 8. | Are there any parameters which have exceeded a daily maximum limit or could cause the company to be out of compliance with a monthly or 4-day average ? | Y | <input checked="" type="radio"/> N | N/A |
| 8a | Are any non-detectable results higher than the permits limits ? | Y | <input checked="" type="radio"/> N | N/A |
| 8b | If the answer to 8a was yes. did the company submit any documentation in support of compliance ? | Y | N | <input checked="" type="radio"/> N/A |
| 9. | Is proper compliance/non-compliance statement provided ? | <input checked="" type="radio"/> Y | N | N/A |
| 10. | If applicable is compliance schedule submitted ? | <input checked="" type="radio"/> Y | N | N/A |
| 11. | Is combined waste stream formula required ? | <input checked="" type="radio"/> Y | N | N/A |
| 12. | If combined waste stream formula was used, have calculations been submitted correctly ? | <input checked="" type="radio"/> Y | N | N/A |
| 13. | Have correct number of samples been submitted ? | <input checked="" type="radio"/> Y | N | N/A |
| 14. | Has sample number been reported in space provided ? | <input checked="" type="radio"/> Y | N | N/A |
| 15. | Have all regulated parameters been listed on MR-1 ? | <input checked="" type="radio"/> Y | N | N/A |
| 16. | Has sample type been stated on MR-1 ? | <input checked="" type="radio"/> Y | N | N/A |
| 17. | Have all samples been taken during this reporting period ? | <input checked="" type="radio"/> Y | N | N/A |
| 18. | Has NJDEPE certified lab been used ? | <input checked="" type="radio"/> Y | N | N/A |
| 19. | Have analytical results been submitted on copies of Laboratory stationery ? | <input checked="" type="radio"/> Y | N | N/A |



- | | | | | |
|------|--|----------|----------|------------|
| 20. | Have results been written in space designated on MR-1? | <u>Y</u> | N | N/A |
| 21. | Have average permit limitations been included on MR-1? | <u>Y</u> | N | N/A |
| 22. | Have maximum permit limitations been included on MR-1? | <u>Y</u> | N | N/A |
| 23. | Is method used to preserve samples stated on MR-1? | <u>Y</u> | N | N/A |
| 24. | If non-use statement is made does regulations allow exemptions ? | Y | <u>N</u> | N/A |
| 25. | Has updated flow diagram been provided ? | Y | <u>N</u> | N/A |
| 26. | If the answer to 25 was yes, was the change to the previous plot plan noted ? | Y | N | <u>N/A</u> |
| 27.. | If the answer to 25 was no or N/A, was the appropriate statement of no-change to diagram submitted ? | <u>Y</u> | N | N/A |
| 28. | Has production rate been provided if production Based Standards were used ? | Y | N | <u>N/A</u> |
| 29. | Has MR-1 been signed by authorized representative ? | <u>Y</u> | N | N/A |
| 29. | Has information been submitted on proper MR-1 form ? | <u>Y</u> | N | N/A |
| 29. | Have any and all PVSC samples taken during this month been averaged in with the company samples ? | Y | N | <u>N/A</u> |

First Reviewer: comments on deficiencies COMPLETE

Date Reviewed 12/17/08 Date sent to user _____

Date due back _____ Reviewer e.j.m.

Second Review comments on deficiencies _____

Date Reviewed _____ Date sent to user _____

Date due back _____ Reviewer _____

Date ok _____ Reviewer _____

10/01/08 THRU 10/31/08

AMNEAL PHARMACEUTICALS

(439)

PATERSON

Local Limits

Parameters	Threshold Value	Local Limit	Over Limit	Additional Tests
Cadmium	0.005	0.19	Certified Non-Use	None
Copper	0.092	3.02		Three Months
Lead	0.029	0.54		
Nickel	0.02	5.9	Certified Non-Use	None
Zinc	1.67	1.67		
Mercury	0.001	0.080		Three Months

Violations: noneCOMPLETE ✓ Yes NoDate 12/17/08

PRETREATMENT MONITORING REPORT

NAME: AMNEAL PHARMACEUTICALS CORPORATION

MAILING ADDRESS: 209 MC LEAN BLVD., PATERSON, NJ 07504

FACILITY LOCATION: 209 MC LEAN BLVD., PATERSON, NJ 07504

CATEGORY & SUBPART: 439 OUTLET #: 1

CONTACT OFFICIAL: JITEN PARIKH TELEPHONE: 973-357-0222

NEW CUSTOMER ID / OUTLET ID: 272-00050-1 OLD OUTLET DESIGNATION: _____

MONITORING PERIOD					
Start			End		
10	01	08	10	31	08
MO	DAY	YR	MO	DAY	YR

	Average	Maximum
Regulated Flow-gal/day	<u>1499</u>	<u>1649</u>
Total Flow-gal/day	<u>3125</u>	<u>3438</u>

Method Used: _____ Flowmeter readings / working days. _____

PLEASE SEE ATTACHMENT

Production Rate (if applicable) _____

PARAMETER		MASS OR CONCENTRATION			# OF SAMPLES	SAMPLE TYPE COMP/GRAB
		MON AVG	MAXIMUM	UNITS		
Cd	Sample Measurement			Mg/l	1	Comp
	Permit Requirement	0.19		Mg/l		
Cu COPPER	Sample Measurement	0.194 ✓		Mg/l	1	Comp
	Permit Requirement	3.02		Mg/l		
Pb LEAD	Sample Measurement	0.194 ✓		Mg/l	1	Comp
	Permit Requirement	0.54		Mg/l		
Hg	Sample Measurement			Mg/l	1	Comp
	Permit Requirement	0.080		Mg/l		
Ni	Sample Measurement			Mg/l	1	Comp
	Permit Requirement	5.9		Mg/l		
Zn ZINC	Sample Measurement	0.215 ✓		Mg/l	1	Comp
	Permit Requirement	1.67		Mg/l		
ACETONE	Sample Measurement	1.740 ✓		Mg/l	1	Grab
	Permit Requirement	8.2		Mg/l		
METHYLENE CHLORIDE	Sample Measurement	ND (<0.069)		Mg/l	1	Grab
	Permit Requirement	0.7		Mg/l		
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					
	Sample Measurement					
	Permit Requirement					

PRETREATMENT MONITORING REPORT

Certification of Non-Use if applicable (use additional sheets):

N/A

NOV 19 2008

Compliance or non compliance statement with compliance schedule (use additional sheets if necessary) for every

parameter used: AMNEAL IS IN COMPLIANCE WITH PVSC LOCAL
LIMITS AS WELL AS ALL 40 CFR 439 PARAMETERSExplain Method for preserving samples: NITRIC ACID TO A PH LESS THAN 2.

I certify under penalty of law that this document and attachments were prepared under my direction or supervision in accordance with a system designed to assure that qualified personnel properly gather and evaluate the information submitted. Based on my inquiry of the person or persons who manage the system, or those persons directly responsible for gathering the information, the information submitted is, to the best of my knowledge and belief, true, accurate and complete. I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing violations.

403.6(a)(2)(ii) revised by 53 FR 40610, October 17, 1988

Senen Roxas

Signature of Principal

Executive or Authorized Agent

for: JITEN PARIKH
VICE PRESIDENT

Type Name and Title

11-17-08

Date

Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: OCT. 22, 2008

PROJECT NO : 813801

LAB ID NO: 813801.1

FIELD ID NO: AP-1014

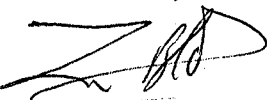
Sample: Liquid, Sampled by CALI on 10/14/08

Analysis	Method Number	Results (mg/L)	Discharge Limitation (mg/L)	RLs (mg/L)	Analysis Date Time	DF
COPPER	200.7	0.194	3.02	0.003	10/20/08 14:28	1
LEAD	200.7	0.0075	0.54	0.005	10/20/08 14:28	1
ZINC	200.7	0.215	1.67	0.005	10/20/08 14:28	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, RLs= Laboratory Reporting Limits,
MDL= Method Detection Limit, DF= Dilution Factor, ND = Not Detected, RL = MDL x DF
All metals analyses performed were subcontracted to NJ certified lab # PA 166

Submitted By:



Zvi Blank, Ph.D., CHMM
Laboratory Director



Ms. Sonal Thakar
Amneal Pharmaceutical Corp..
209 McLean Blvd
Paterson, NJ 07054

ANALYSIS REPORT

REPORT DATE: OCT.22, 2008

PROJECT NO : 813801

LAB ID NO: 813801.2

FIELD ID NO: AP-1014 G

Sample: Liquid, Sampled by CALI on 10/14/08

Analysis	Method Number	Results (µg/L)	Discharge Limitation (mg/L)	RLs (µg/L)	Analysis Date	DF
ACETONE	EPA Method 624	1740	8.2	176	10/17/08	1
METHYLENE CHLORIDE	EPA Method 624	ND(<69.0)	0.7	69.0	10/17/08	1

Definitions:

pH Unit, J= Compound Detected but Below MDL, RLs= Laboratory Reporting Limits,
MDL= Method Detection Limit, DF= Dilution Factor, ND = Not Detected, RL = MDL x DF
Analyses performed were subcontracted to NJ certified lab # 07010

Submitted By:



Zvi Blank, Ph.D., CHMM
Laboratory Director





QC Laboratories®

Analytical Report



MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

Regarding:

MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

Account No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA
Project No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA

P.O. No:
PWSID No:

Inv. No: 1018120

Sample Number L2802835-1
Sample Description 813801.1 COMPOSITE
Samp. Date/Time/Temp 10/14/08 10:41am NA F
Sampled by Customer Sampled
Received Temp 37 F Iced (Y/N): Y

Parameter	Method	Result	RLs	Test Date, Time, Analyst
COPPER	EPA 200.7	0.194 mg/l	0.00300 mg/l	10/20/08 02:28PM GJH
LEAD	EPA 200.7	0.00750 mg/l	0.00500 mg/l	10/20/08 02:28PM GJH
ZINC	EPA 200.7	0.215 mg/l	0.00500 mg/l	10/20/08 02:28PM GJH

Thomas J. Hines
Thomas J. Hines, President

QC Laboratories

Analytical Report



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COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
BUILDING #4/C
PARSIPPANY, NJ 07054-4909

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Project No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA

P.O. No:
PWSID No:

Inv. No: 1018120

Sample Number L2802835-2
Sample Description 813801.2 GRAB
Samp. Date/Time/Temp 10/14/08 10:42am NA F
Sampled by Customer Sampled
Received Temp 37 F Iced (Y/N): Y

Parameter	Method	Result	RLs	Test Date, Time, Analyst
CHLOROMETHANE	EPA 624	ND ug/l	62.0 ug/l	10/17/08 05:48AM MPL
VINYL CHLORIDE	EPA 624	ND ug/l	65.0 ug/l	10/17/08 05:48AM MPL
BROMOMETHANE	EPA 624	ND ug/l	114. ug/l	10/17/08 05:48AM MPL
CHLOROETHANE	EPA 624	ND ug/l	109. ug/l	10/17/08 05:48AM MPL
TRICHLOROFLUOROMETHANE	EPA 624	ND ug/l	98.0 ug/l	10/17/08 05:48AM MPL
1,1-DICHLOROETHENE	EPA 624	ND ug/l	75.0 ug/l	10/17/08 05:48AM MPL
ACETONE	EPA 624	1740 ug/l	176. ug/l	10/17/08 05:48AM MPL
METHYLENE CHLORIDE	EPA 624	ND ug/l	69.0 ug/l	10/17/08 05:48AM MPL
TRANS-1,2-DICHLOROETHENE	EPA 624	ND ug/l	45.0 ug/l	10/17/08 05:48AM MPL
1,1-DICHLOROETHANE	EPA 624	ND ug/l	48.0 ug/l	10/17/08 05:48AM MPL
CARBON TETRACHLORIDE	EPA 624	ND ug/l	72.0 ug/l	10/17/08 05:48AM MPL
CHLOROFORM	EPA 624	ND ug/l	56.0 ug/l	10/17/08 05:48AM MPL
1,1,1-TRICHLOROETHANE	EPA 624	ND ug/l	52.0 ug/l	10/17/08 05:48AM MPL
BENZENE	EPA 624	ND ug/l	61.0 ug/l	10/17/08 05:48AM MPL
1,2-DICHLOROETHANE	EPA 624	ND ug/l	49.0 ug/l	10/17/08 05:48AM MPL
TRICHLOROETHENE	EPA 624	ND ug/l	66.0 ug/l	10/17/08 05:48AM MPL
1,2-DICHLOROPROPANE	EPA 624	ND ug/l	52.0 ug/l	10/17/08 05:48AM MPL
BROMODICHLOROMETHANE	EPA 624	ND ug/l	52.0 ug/l	10/17/08 05:48AM MPL
TOLUENE	EPA 624	ND ug/l	54.0 ug/l	10/17/08 05:48AM MPL
TRANS-1,3-DICHLOROPROPENE	EPA 624	ND ug/l	51.0 ug/l	10/17/08 05:48AM MPL
CIS-1,3-DICHLOROPROPENE	EPA 624	ND ug/l	45.0 ug/l	10/17/08 05:48AM MPL
1,1,2-TRICHLOROETHANE	EPA 624	ND ug/l	37.0 ug/l	10/17/08 05:48AM MPL
2-CHLOROETHYL VINYL ETHER	EPA 624	ND ug/l	62.0 ug/l	10/17/08 05:48AM MPL
DIBROMOCHLOROMETHANE	EPA 624	ND ug/l	46.0 ug/l	10/17/08 05:48AM MPL
TETRACHLOROETHENE	EPA 624	ND ug/l	54.0 ug/l	10/17/08 05:48AM MPL
CHLOROBENZENE	EPA 624	ND ug/l	67.0 ug/l	10/17/08 05:48AM MPL
ETHYL BENZENE	EPA 624	ND ug/l	53.0 ug/l	10/17/08 05:48AM MPL
BROMOFORM	EPA 624	ND ug/l	45.0 ug/l	10/17/08 05:48AM MPL
1,1,2,2-TETRACHLOROETHANE	EPA 624	ND ug/l	61.0 ug/l	10/17/08 05:48AM MPL
1,3-DICHLOROBENZENE	EPA 624	ND ug/l	48.0 ug/l	10/17/08 05:48AM MPL
1,4-DICHLOROBENZENE	EPA 624	ND ug/l	59.0 ug/l	10/17/08 05:48AM MPL
1,2-DICHLOROBENZENE	EPA 624	ND ug/l	55.0 ug/l	10/17/08 05:48AM MPL

**** NOTES CONCERNING THE ABOVE SAMPLE ****

Thomas J. Hines
Thomas J. Hines, President

QC Laboratories

Analytical Report



MS. HAYA BLANK
COMPLETE ANALYSIS LABORATORIES, INC.
1259 ROUTE 46
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Regarding:

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Project No: W05307, COMPLETE ANALYSIS 1 WK TAT PHILLY QA

P.O. No:
PWSID No:

Inv. No: 1018120

A dilution was required to be performed on this sample because of the sample matrix and/or interferences by non-target compounds. The surrogate recoveries may have been impacted. The RL's have been adjusted to reflect the dilution.

- A result of "ND" indicates the concentration of the analyte tested was either not detected or below the RLs.
 - All analysis, except field tests are conducted in Southampton, PA unless otherwise identified.
 - The test "pH lab" is analyzed upon receipt in the laboratory, the result will not be suitable for regulatory purposes.
 - Actual times of analysis for parameters reported <24 hrs are available upon request. All testing is completed within the required holding time unless otherwise noted.
 - Definitions: ND=not detected; NEG=negative; POS=positive; COL=colonies; RLs=Laboratory reporting limits; L/A=laboratory accident; TNTC=too numerous to count.
 - A result marked with "DRY" indicates that the result was calculated and reported on a dry weight basis.
 - QC NELAP ID's: PA 09-00131, NJ PA166, FL E87954, NY 11223, CT PH-0768, DE PA-018, KY 90228, MD 206, EPA PA00018, Bioassay: PA 09-03574, NJ PA034, FL E87953, KS E10373, SC 89020001.
 - QC STATE ID's: Wind Gap, NJ PA001, PA 48-01334; E RUTHERFORD NJ02015; Vineland NJ06005; Reading PA 06-03543.
 - All samples are collected as "grab" samples unless otherwise identified.
 - MCL= is the EPA recommended "maximum contaminant level" for a parameter, PLs=customer specific permit limits.
- Regulatory authorities are assessing substantial fines for testing omissions. Please track your sample collections and results on a weekly, monthly, or quarterly basis to ensure compliance. QC's internet program 'LIVE ACCESS' will provide you with real-time access to collection dates and results. Please contact Customer Service for further information on acquiring LIVE ACCESS.

Thomas J. Hines
Thomas J. Hines, President



METHOD USED

TOTAL WATER USED

$7,307.6 (10/31/08) - 7,211.5 (10/1/08) = 96 \text{ CF1} \times 7.48 \times 100 = 71,883/23 \text{ DAYS} = 3,125 \text{ Total Flow - Gal/Day.}$

SANITARY USED

$1,614 (10/31/08) - 1,564 (10/1/08) = 50 \times 7.48 \times 100 = 37,400/23 \text{ DAYS} = 1,626 \text{ Flow - Gal/Day.}$

$\text{REGULATORY/TOTAL} = 1,499/3,125 = 0.5$

SITE PLAN: NO CHANGE



METHOD USED

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$7,307.6 (10/31/08) - 7,211.5 (10/1/08) = 96 \text{ CF1} \times 7.48 \times 100 = 71,883/23 \text{ DAYS} = 3,125 \text{ Total Flow - Gal/Day.}$

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$\text{REGULATORY/TOTAL} = 1,499/3,125 = 0.5$

SITE PLAN: NO CHANGE



November 17, 2008

Mr. Andy Caltagirone
Manager of Industrial & Pollution Control
Passaic Valley Sewerage Commissioners
600 Wilson Ave.
Newark, NJ 07105

Dear Mr. Caltagirone:

Enclosed are MR-2 and MR-1 periodic compliance monitoring reports, which are due on 11/21/08 and 12/4/08, respectively.

Thank you.

Sincerely yours,

for: Suren Poxar
Jiten Parikh
Vice President

DROP DOWN BOX**NON USE CERTIFICATION MONITORING REPORT
LOCAL LIMITS**NAME: AmNEAL PHARM.

MAILING ADDRESS: _____

FACILITY LOCATION: _____

CATEGORY & SUBPART _____ PERMIT # _____ OUTLET #: 27200050-1

CONTACT OFFICIAL: _____ TELEPHONE #: _____

I have been authorized to certify non-use for the following heavy metals:

Arsenic _____	Lead <input checked="" type="checkbox"/>	Zinc _____	SAMPLE DATE			
Cadmium _____	Mercury _____		MONTH	DAY	YEAR	
Chromium _____	Molybdenum _____		10	14	08	
Copper _____	Nickel _____					

PARAMETER		CONCENTRATION			SAMPLE TYPE
		RESULT	THRESHOLD VALUE EXCEEDED YES OR NO	UNITS	COMP/GRAB
LEAD	Sample Measurement	0.0075	n	mg/l	Comp.
	Threshold Value	0.029		1	
METHYLENE CHLORIDE	Sample Measurement	< 0.069	n	↓	GRAB
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
	Sample Measurement				
	Threshold Value				
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SB